Application Number: PCT/US95/01103

Title: MEDICAL DIAGNOSIS, TREATMENT AND IMAGING SYSTEMS

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Applicant: Biosense, Ltd.

<u>LETTER ACCOMPANYING AMENDMENT</u>

This communication is in response to a written opinion dated July, 9 1996 in the above referenced application. This letter is accompanied by new claims 1-68 contained on replacement pages 40-49. Page 50 is canceled. Claims 1, 29, 33 and 40 have been amended. Claim 58 and 59 have been canceled and the succeeding claims have consequently been renumbered. The following discussion refers to the claims as now numbered. References to the specification are to the published version thereof.

The applicants thank, Mr. Stern, the Examiner in charge of the application for the courteous interview granted to Dr. Shlomo Ben-Haim, one of the inventors and applicants' agent, Dr. Paul Fenster on September 26, 1996. The following remarks and the amendments in the accompanying claims include changes to the claims agreed to at the interview.

<u>Invention 1</u>

The independent claims in this invention (claims 1 and 33) were rejected, in the written opinion, as being anticipated by D1. During the interview D3 was also mentioned by the Examiner as being relevant to these claims.

Both claims 1 and 33 require the computing of the six dimensions for position and orientation in response to the signals generated by the sensors. Neither D1 nor D3 teaches the finding of the six dimensions of position and orientation, <u>inter alia</u> since neither uses such six dimensions. In particular D1 (references are to the English language version, US 5,295,486) at col. 3, lines 55-64 (the portion cited by the Examiner) and the following paragraph describe the calculation of position using two sensors and two field induction loops. Such a system can <u>not</u> generate the required six dimensions. In the next following

paragraph orientation is mentioned but it is not a parameter to be measured but rather in terms of determination if some favored position or orientation is achieved. In particular, there is neither motivation nor structure in D1 for finding six dimensions of position and orientation.

Applicants have amended claim 1 to make clear that the six dimensions are calculated in response to the signals generated by the sensor coils. This is already explicit in claim 33, which has however, been amended in other respects for improved clarity.

With respect to D3, here again there is a failure of both motivation and structure. First, since the coils are all axially directed, they cannot be used determine the orientation angle about the axis of the catheter (the "roll"), which is one of the three dimensions of orientation. Furthermore, for the use described in D3 there is no need for this orientation. In fact the reference at page 2, lines 2-3 and 32-33; page 3, lines 10-11 and 21-26; and page 5, lines 5-9 and 30 et seq. describes only determination of position. Furthermore page 9, lines 20-24 and page 9, line 32 to page 16, line 16 describe the determination of the position and two dimensions of orientation.

Furthermore, there is no reason given for determining the third orientation to carry out the purposes of the reference.

For this reason neither D1 or D3 anticipate invention 1 as claimed or make it obvious.

Invention 2

Three independent claims are used to define this invention, namely claims 29, 37 and 60. These claims were rejected in the written opinion as being anticipated by D2. However, each of the claims contains limitations which are not found in the D2.

In particular, claim 29 describes manipulating the distal end of the catheter. D2 does not manipulate the distal end of the catheter but rather keeps it fixed and manipulates a transducer which is movable within the fixed catheter. Claim 37 includes the requirement that the six dimensions of position and orientation of the transducer be determined for each representation. However, D2 does not determine any position and does not determine all three orientations of the transducer. Finally, claim 60 includes

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taking measurements at a plurality of <u>positions</u> and orientations and utilizing the measurements to form an image of a surface. D2 makes all the measurements from a single position.

The Examiner refused to examine claims 37-39 as being directed to a "surgical method of treatment." However, the claim is directed to a method of imaging and not to a method of treatment. Furthermore, no surgical activity is either explicit or implicit in claim 37, the claimed method being equally applicable to a method of imaging the colon for example. Nor, under the rules, is a surgical method of <u>imaging</u> excluded from examination under the PCT. The relevant PCT rule (67.1(iv)) reads: "methods for treatment of the human or animal body by surgery or therapy as well as diagnostic methods." According to this rule only surgical <u>treatment</u> methods are excluded. All diagnostic methods are excluded, however, medical <u>imaging</u> methods are not diagnostic methods, <u>per se</u> and are not excluded. In this regard Applicants note that there is nothing in the rules which makes any distinction between surgical and non-surgical methods of diagnosis. If surgical imaging methods are excluded as being diagnostic, then so should non-surgical imaging methods such as X-ray, CT, MRI and Nuclear Medicine imaging methods. However, long tradition sanctions such claims.

Invention 3

This invention is now represented by only one independent claim, namely, claim 58. This claim was rejected as being anticipated by D6 (Figs. 9, 10; page 5, lines 12-35; and page 14, line 21 to page 15, line 19). However, D6 does not teach at least one element of claim 58, namely, a "flat relatively flexible portion being slit alone a portion of the length thereof." The embodiment covered by this claim is shown in Fig. 10 of the present application and does not corresponding to any disclosure in D6.

Invention 4

This invention includes one independent claim, namely claim 40. Claim 40 as originally presented distinguished over the cited

prior art, D3, in that it required that the multiple field sensors be "proximate to the distal end." In D3 where two or more coils are utilized they are described as "two or more sensing coils may be mounted in spaced relationship along the length of the probe, <u>one</u> preferably being located adjacent the tip of the probe and the <u>others removed from the tip."</u> (Emphasis added.)

The dictionary defines "proximate" as being "very near," which is diametrically opposed to the teaching of D3 which requires a spacing for its proper operation.

In order to further distinguish the claim from the prior art claim 40 has been amended to add that the sensors have a fixed orientation between them. In D3, the sensors do not have such a fixed orientation. For the basis for this change see the discussion below of the "new" material rejection of claim 29 (in particular, page 25, lines 8-10).

FORMAL MATTERS

1) The Examiner suggested in the written opinion that claim 29 had been amended, in the amendment accompanying the demand under Chapter II, by adding undisclosed subject matter. Applicants disagree. As was explained by applicants' agent at the interview, the added feature is implicit from the disclosure and is clearly evident to a person of skill in the art who reads the specification. In particular, the transducer is defined at page 28, lines 16-17 as being "forward looking." Furthermore, the specification describes the requirement of changing the orientation of the device without changing its position by a great amount (page 28, lines 22-25). Additionally, the method given for changing the orientation is to change the orientation of the distal end of the catheter as a whole. Furthermore, the transducer is described as being contained in a relatively rigid housing attached to the distal end (page 29, lines 10-14). The transducer and the sensor are described as being rigidly attached "so that measurement of the position and orientation of the locating sensor will the position and orientation of the active portion" (page 29, line 24-28). Finally, on page 25, lines 8-10 the three sensors are described as having a "fixed and known

location and orientation in the remote object reference frame," a remote object being, for example, a medical instrument, such as a catheter (see page 27, lines 3-4 and 12).

From all of these statements (and from Fig. 14) it is clear that in at least some of the described embodiments the sensors are fixed with respect to the distal end of the catheter and with respect to the sensor so that the addition to claim 29 is well based on the disclosure. Applicants note that the amendment is not required for patentability (see the above discussion of Invention 2) but was added to further clarify the invention and to further distinguish it from the prior art.

2) Formal changes to the claims have been required by the examiner to place them in European form (section VII, items 1-4). Since the present application will form the basis for applications in many different countries with varying rules of claim structure and different requirements for citing prior art in the disclosure. In view of this fact applicants will defer carrying out these requirements until the National stage. At that time, the claim structure and specification will be adapted to local rules and practice. Of course, we expect that these observations will be included in the IPER.

3) Claim 1 has been amended to overcome the objection to the use of the word "point."

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MEDICAL DIAGNOSIS, TREATMENT AND IMAGING SYSTEMS

FIELD OF THE INVENTION

The present invention relates to medical diagnosis, treatment and imaging systems. More particularly, the present invention relates to medical probes whose location can be detected and adjusted and which have an additional detection, imaging and/or treatment function.

BACKGROUND OF THE INVENTION

Probes, such as catheters, suitable for various medical procedures and internal imaging, are fairly common. Such probes include: balloon angioplasty catheters, catheters with laser-, electrical- or cryo-ablation characteristics, catheters having ultrasound imaging heads, probes used for nearly incisionless-surgery or diagnosis, and endoscopes. Where such probes are used for treatment, the probes must be carefully positioned in relation to the body structure. Even for imaging systems such as ultrasound systems, some positioning capability has been described.

In cardiovascular examinations and in particular in those using invasive techniques, multiple catheters are inserted into the vascular system and then advanced towards the cardiac chambers. The procedure itself is generally performed under fluoroscope guidance which necessitates the use of a continuous source of x-ray as a transillumination source. The image generated using the fluoroscope is a 2D display of the anatomy with the location of the catheter superimposed. The anatomy can be viewed with a relatively low resolution since the cardiac chamber and the blood vessels are transparent to the x-ray radiation.

More recently, several technologies have been developed to ease the process of cardiac catheterization, mainly by enabling the physician to follow the path of the tip of the catheter inside the blood vessel. Some of this technology is based on digital subtraction radiography technology that enables viewing the blood vessel after the injection of a radio contrast dye and superimposing on that image the path

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1 of the catheter. These technologies necessitate the use of
2 radiopaque dyes which are a major cause of morbidity in
3 high-risk patients during cardiac catheterization.
4   U.S. Patent No. 5,042,486 to Pfeiller et al., the
5 disclosure of which is incorporated herein by reference,
6 describes a method in which the position of a catheter tip
7 is located using electromagnetic fields. The catheter is
8 introduced and the tip location is followed. The path of
9 the tip is superimposed on the pre-registered image of the
10 blood vessel or the organ, through which the catheter was
11 advanced. However, this technology requires acquisition and
12 processing of images prior to the procedure and involves a
13 highly sophisticated and time-consuming procedure for the
14 correct alignment of the image acquired previous to this
15 procedure, and the orientation and location of the blood
16 vessel or the organ during the catheterization procedure
17 itself.
18   U.S. Patent 4,821,731 to Martinelli et al., the
19 disclosure of which is incorporated herein by reference,
20 discloses a method for internal imaging of a living body
21 using ultrasound. In this patent the position of an
22 ultrasound imaging catheter is determined by computing the
23 relative position of the catheter using the response of an
24 ultrasound transducer to a reference signal and by computing
25 the angular orientation of the catheter about its axis by
26 determining the signal induced in a single coil by
27 substantially perpendicular magnetic fields of different
28 frequencies. The ultrasound transducer is also used to send
29 and detect ultrasound signals in a direction perpendicular
30 to the catheter axis. By rotating the catheter and moving it
31 along its axis an ultrasound image may be generated. The
32 catheter is also described as being capable of transmitting
33 a laser beam to the end thereof to ablate tissue from
34 lesions on the walls of arteries.
35   A catheter which can be located in a patient using an
36 ultrasound transmitter located in the catheter, is disclosed

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1 in U.S. Patent No. 4,697,595 and in the technical note
2 "Ultrasonically Marked Catheter, a Method for Positive
3 Echographic Catheter Position and Identification", Bryer et
4 al., Medical and Biological Engineering and Computing, May,
5 1985, pages 268-271. Also, U.S. Patent No. 5,042,486
6 discloses a catheter which can be located in patients using
7 non-ionizing fields and suitably imposing catheter location
8 on a previously obtained radiological image of the blood
9 vessel.

10   PCT Patent Publication WO 94/0938, the disclosure of
11 which is incorporated herein by reference, describes a
12 system using a single-coil type sensor which is coaxial with
13 the long axis of a catheter and which senses fields which
14 are generated by three multicoil generators external to the
15 body of a patient.

16   Other methods and apparatus for the determination of
17 the position of a catheter or endoscope are shown in U.S.
18 Patents   5,253,647;   5,057,095;   4,095,698;   5,318,025;
19 5,271,400; 5,211,165; 5,265,610; 5,255,680; 5,251,635 and
20 5,265,611.

21   U.S. Patent No. 3,644,825 describes a system which uses
22 the relative motion of a sensor in the determination of its
23 position. The relative motion supplies information to the
24 sensing coils needed to identify position and orientation.
25 However, such a solution is not applicable to identifying
26 position and location of the object where there is no
27 relative motion between the object and the reference frame.
28   U.S. Patent No. 3,868,565, the disclosure of which is
29 incorporated herein by reference, comprises a tracking
30 system for continuously determining the relative position
31 and orientation of a remote object. This tracking system
32 includes orthogonally positioned loops for both a plurality
33 of sensors and a plurality of radiating antennas. With the
34 proper excitation currents to those loops, the radiating
35 antennas generate an electromagnetic field that is radiated
36 from those antennas to the sensor. The tracking system

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1   operates as a closed loop system where a controlling means
2   measures the field that is received at the sensor at the
3   remote object and feeds the information back to radiating
4   antennas to provide a nutating field radiating as a pointing
5   vector towards the remote object. Accordingly, the pointing
6   vector gives the direction to the sensing antenna from the
7   radiating antenna.

8   Similarly, Kuipers describes in his U.S. Patent No.
9   4,017,858, the disclosure of which is incorporated herein by
10 reference, an electromagnetic field which rotates about a
11 pointing vector and is used both to track or locate the
12 remote object in addition to determining the relative
13 orientation of the object. This system, wherein the
14 radiating coils are charged with the properly designed wave
15 forms, generates a magnetic field which, in a closed loop
16 manner, can be fed into processing means to generate the
17 information needed to determine an orientation of a remote
18 object.

19   U.S. Patent No. 4,054,881, the disclosure of which is
20 incorporated herein by reference, describes a non-tracking
21 system for determining the position and location of a remote
22 object with respect to a reference frame. This is
23 accomplished by applying electrical signals to each of three
24 mutually-orthogonal, radiating antennas, the electrical
25 signals being multiplexed with respect to each other and
26 containing information characterizing the polarity and
27 magnetic moment of the radiated electromagnetic fields. The
28 radiated fields are detected and measured by the three
29 mutually orthogonal receiving antennas having a known
30 relationship to the remote object, which produce nine
31 parameters. These nine parameters, in combination with one
32 known position or orientation parameter, are sufficient to
33 determine the position and orientation parameters of the
34 receiving antennas with respect to the position and
35 orientation of the radiating antennas.

36   U.S. Patent No. 4,849,692, the disclosure of which is
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1 incorporated herein by reference, describes a quantitative
2 method for measuring the relative position and orientation
3 of two bodies in the presence of metals. Measuring the
4 position and orientation of receiving antennas with respect
5 to the transmitting antennas is achieved using direct
6 current electromagnetic field signals. Electromagnetic
7 radiation is designed to be transmitted in a sequence by
8 each of the mutually orthogonal radiating antennas. A
9 receiving antenna measures the values of transmitted direct
10 current magnetic fields, one dimension at a time, and those
11 of the earth's magnetic field as well. This method requires
12 repetitive acquisition and computations to determine
13 position and location of remote objects.
14   Other methods which are known in the art for
15 determining multi-dimensional positioning and orientation
16 for aircraft and for helmets are described in U.S. Patent
17 4,849,692, European patent publication 0 576 187 A1, GB
18 patent publication 2 197 078 A and U.S. Patent 4,314,251 the
19 disclosures of which are incorporated herein by
20 reference.
21   The above described prior art which is for use in non-
22 medical applications, utilizes sensors and other structures
23 which are not suitable for use in catheters. Those
24 references which are described as being useful for medical
25 probes generally give less than six dimensional information
26 (three position coordinates and three angular coordinates).
27   In previous, as yet unpublished applications assigned
28 to the assignee of the present application, U.S. Patent
29 Application Number 08/094,539, filed July 20, 1993 and PCT
30 Application PCT/US94/08352 filed July 20, 1994, the
31 disclosures of which are incorporated herein by reference, a
32 system is disclosed which incorporates a catheter which
33 includes a position measuring device which can determine the
34 position of the catheter in three dimensions, but not its
35 orientation. In these applications, this catheter is used to
36 map the electrical activity at the inner walls of the heart

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1   and to ablate portions of the heart muscle in response to

2   such mappings. The position of the catheter used for the

3   mapping/ablation function is determined with reference to

4   three position detecting devices which are positioned

5   against the inner wall of the heart at three different

6   stable locations to form a reference plane.

7   **SUMMARY OF THE INVENTION**

8   In general the present application discloses a catheter

9   locating means and method that offers quantitative, high

10   resolution locating information that, when assimilated with

11   sensed local information results in a high resolution,

12   detailed map of the information. This map may optionally be

13   superimposed on an image or other representation of the

14   organ architecture.

15   The locating means preferably generates continuous

16   location and orientation information concerning a remote

17   object, in particular a catheter, relative to a reference

18   frame, in a non-iterative manner.

19   One aspect of the present invention relates to the

20   provision of a new six-dimensional positioning apparatus

21   suitable for use with a catheter.

22   In a preferred embodiment of this system, a plurality

23   of non-concentric coils are placed in a catheter adjacent a

24   locatable site, for example, its distal end. The coils

25   preferably have orthogonal axis. The relative positioning of

26   the coils differs from that described in the prior art in

27   that the coils are separated in space and are not

28   concentric. These coils generate signals in response to

29   externally applied magnetic fields which allows for the

30   computation of six position and orientation dimensions.

31   A second aspect of the present invention is directed

32   toward a new method for computing multi-dimensional position

33   and orientation of a coil system from signals produced by

34   the coils in response to a system of externally applied

35   electromagnetic fields.

36   A third aspect of the present invention allows for the

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1 mapping of the interior of the heart in a manner similar to
2 that described in the above-referenced patent applications
3 assigned to the assignee of the present application, with
4 the simplification that only a single six-dimensional
5 location/orientation detection sensor is used for reference.
6 A fourth aspect of the present invention involves an
7 ultrasonic or other imaging probe having a six-dimensional
8 positioning capability in response to external
9 electromagnetic fields. Use of such a probe obviates the use
10 of ionizing radiation or sonic sensing for position
11 determination and gives ultrasonic or other imaging
12 information whose direction and orientation is completely
13 known.
14 A fifth aspect of the invention involves methods and
15 apparatus for adding a controlled change in orientation to a
16 catheter, thereby to allow for maneuvering of the cathode
17 and its easy placement.
18 A sixth aspect of the invention utilizes the controlled
19 change in orientation to allow for two or three-dimensional
20 imaging using a non-scanning probe, such as an ultrasound
21 probe or for three-dimensional scanning using a two-
22 dimensional scanning probe.
23 There is therefore provided, in accordance with a
24 preferred embodiment of the invention, a locating system for
25 determining the location and orientation of an invasive
26 medical instrument, for example a catheter or endoscope,
27 relative to a reference frame, comprising:
28 a plurality of field generators which generate known,
29 distinguishable fields, preferably continuous AC magnetic
30 fields, in response to drive signals;
31 a plurality of sensors situated in the invasive medical
32 instrument proximate the distal end thereof which generate
33 sensor signals in response to said fields; and
34 a signal processor which has an input for a plurality
35 of signals corresponding to said drive signals and said
36 sensor signals and which produces the three location

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1 coordinates and three orientation coordinates of a point on
2 the invasive medical instrument.

3   Preferably one or both of the plurality of field
4 generators or sensors comprises three distinguishable, non-
5 overlapping, generators or sensors.

6   In a preferred embodiment of the invention, each sensor
7 comprises a coil. Preferably, said plurality of coils have
8 axes which intersect within a coil. When said plurality of
9 coils comprises three coils, said coils preferably have axes
10 which do not all intersect in a point.

11   Preferably, the signal processor cross-correlates the
12 signals corresponding to the drive and sensor signals.

13   Preferably, the fields generated by each of the
14 generators have a different frequency, a different phase, or
15 both a different frequency and a different phase.

16   In a preferred embodiment of the invention the field
17 generated by each field generator has a different frequency,
18 preferably frequencies which are each integer multiples of a
19 given frequency. Preferably, the duration of the cross-
20 correlation of the inputs is the minimal common product of
21 the integer multipliers divided by the given frequency.

22   Preferably, the results of the cross-correlation are
23 used to calculate the contribution of each field generator
24 to the signal generated by each said sensor.

25   In a preferred embodiment of the invention the locating
26 system includes a display system for displaying the position
27 of the point on the invasive medical instrument.

28   Preferably, the locating system further comprises a
29 reference instrument which includes a plurality of non-
30 overlapping sensors situated in the reference instrument
31 which sensors generate sensor signals in response to said
32 fields, wherein said display system displays the position of
33 the point on the invasive medical instrument relative to the
34 position of a point on the reference instrument. Preferably
35 the reference instrument is an invasive medical instrument.
36 Preferably, the sensors are situated proximate the distal

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1 end of the reference invasive medical instrument.

2   In a preferred embodiment of the invention the locating

3 system includes an additional sensor on a portion of the

4 invasive medical instrument which senses a local condition.

5   Preferably, the additional sensor senses local

6 electrical signals, for example electrical signals from the

7 endocardium of the patient's heart, and transfers them to

8 terminals external to the patient's body.

9   In a preferred embodiment of the invention the signal

10 processor processes the position and orientation coordinate

11 signals and the local electrical signals acquired at a

12 plurality of points on the endocardium to generate a map

13 that represents the propagation of electrical signals

14 through tissue in the patient's body.

15   In a preferred embodiment of the invention the

16 additional sensor supplies electrical energy to the

17 endocardium for ablating a portion of the endocardium.

18   Preferably the locating system includes an electrode

19 adapted for supplying electrical energy to the endocardium

20 for ablating a portion of the endocardium.

21   In a preferred embodiment of the invention the

22 additional sensor is an ultrasonic transmitter/receiver.

23   Preferably, the ultrasonic transmitter/receiver

24 provides a less than three dimensional representation of the

25 acoustic properties of tissue beyond the distal end.

25   In a preferred embodiment of the invention, the distal

27 end is deflectable. Preferably, the system includes image

28 reconstruction circuitry which receives a plurality of said

29 less than three dimensional representations acquired at

30 different orientations of the distal end and produces a

31 three dimensional map of the acoustic properties of tissue

32 at least partially surrounding the distal end.

33   There is further provided, in accordance with a

34 preferred embodiment of the invention, an imaging system for

35 intrabody ultrasonic imaging comprising:

36   a invasive medical instrument, preferably, a catheter

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1   or endoscope, having an axial-looking ultrasonic imaging
2   transducer at the distal end thereof which generated a
3   representation, preferably a one or two dimensional
4   representation, of the acoustic properties of tissue beyond
5   the distal end;
6   means for manipulating the distal end to change the
7   orientation thereof; and
8   image reconstruction circuitry which receives a
9   plurality of said representations acquired at different
10 orientations of the distal end and produces a three
11 dimensional map of the acoustic properties of tissue at
12 least partially surrounding the distal end from said
13 plurality of representations.
14   Preferably, the imaging system further comprises:
15   a plurality of field generators which generate known,
16 distinguishable fields in response to drive signals;
17   a plurality of sensors situated in the invasive medical
18 instrument proximate the distal end thereof which generate
19 sensor signals in response to said fields; and
20   a signal processor which has an input for a plurality
21 of signals corresponding to said drive signals and said
22 sensor signals and which produces three location coordinates
23 and three orientation coordinates of the a point on the
24 transducer.
25   There is further provided a method of determining the
26 position and orientation of an invasive medical instrument,
27 for example a catheter or endoscope, having a distal end,
28 comprising:
29   (a) generating a plurality, preferably three, of
30 distinguishable, geometrically different AC magnetic
31 fields;
32   (b) sensing the AC magnetic fields at the sensors at a
33 plurality of points proximate the distal end; and
34   (c) computing six dimensions of position and
35 orientation of a portion of the invasive medical instrument
36 responsive to signals representative of the generated
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1 magnetic fields and the sensed magnetic fields.

2 Preferably, the AC magnetic field is sensed at three
3 points of the invasive medical instrument.

4 There is further provided, in accordance with a
5 preferred embodiment of the invention, an ultrasonic intra-
6 body imaging method comprising:

7 (a) inserting an ultrasonic transducer into the body,
8 said ultrasonic transducer producing a representation of the
9 acoustic properties of tissue beyond an end of the
10 transducer;

11 (b) manipulating the orientation of the transducer to
12 provide a plurality of said representations; and

13 (c) constructing a three dimensional map of the
14 acoustic properties of the tissue in a region at least
15 partially surrounding the end of the transducer from said
16 plurality of representations.

17 Preferably, the method includes determining the six
18 dimensions of position and orientation of the transducer for
19 each of the representations.

20 Preferably, the representation is a less than three
21 dimensional representation.

22 There is further provided an invasive medical
23 instrument, for example a catheter or endoscope, comprising
24 a plurality of magnetic field sensors, preferably coils,
25 proximate the distal end thereof.

26 Preferably the plurality of coils have axes which
27 intersect within a coil. Where the plurality is three, the
28 said coils have axes which do not all intersect in a point.

29 In a preferred embodiment of the invention, the
30 instrument comprises an ultrasound transducer at said distal
31 end. Preferably, the ultrasound transducer provides a
32 representation, preferably a one or two dimensional
33 representation, of the acoustic properties of tissue beyond
34 and along the axis of the catheter.

35 In a preferred embodiment of the invention, the
36 instrument further comprises an electrical probe at said

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1   distal end. The probe is preferably adapted to sense
2   electrical signals generated by tissue which is in contact
3   and conduct said signals to the proximal end of the catheter
4   and/or to supply an ablative electrical signal to tissue
5   contacting said terminal. In a preferred embodiment of the
6   invention, the instrument includes a sensor for measuring
7   local chemistry at the distal end.

8   Preferably, the instrument includes means for changing
9   the orientation of the distal end.

10   There is further provided, in accordance with a
11 preferred embodiment of the invention, apparatus for
12 steering the distal end of an invasive medical instrument,
13 such as a catheter or endoscope, comprising:

14   a relatively more flexible wire passing through the
15 catheter that is attached to the distal end and has a bend
16 near the distal end;

17   a relatively more rigid sleeve which is straight near
18 the distal end and which slideably holds the wire thereat,
19 whereby when the sleeve is slid over the wire, the wire and
20 distal end are straightened.

21   Preferably, the instrument has a lengthwise axis and
22 the wire is sited off the axis of the instrument.

23   There is further provided apparatus for steering the
24 distal end of an invasive medical instrument comprising:

25   a flat relatively flexible portion being slit along a
26 portion of the length thereof to form two portions which are
27 attached at a first end thereof, said first end being
28 attached to the distal end of the instrument;

29   a pair of wires, one end of each of which being
30 attached to one of said portions at a second end thereof;
31 and

32   means for changing the relative lengths of the wires
33 whereby the flexible element is bent, thereby steering the
34 distal end of the instrument.

35   There is further provided, in accordance with a
36 preferred embodiment of the invention, a method of producing

1   a three dimensional image of the internal surface of an

2   internal body organ comprising:

3   measuring the distance to said surface at a plurality

4   of orientations from within the internal surface; and

5   assembling the distances to form an image of the

6   surface.

7   Preferably, the measurement of distances is made from a

8   plurality of points within the organ. Preferably, the

9   measurement of distances is preformed utilizing an

10   ultrasonic transducer.

11   BRIEF DESCRIPTION OF THE DRAWINGS

12   Fig. 1 is a pictorial representation of the application

13   of a system for six-dimensional position and bearing

14   determination, in accordance with a preferred embodiment of

15   the invention to a catheter located in a human body;

16   Fig. 2 is a schematic, cut-away illustration of a

17   generalized catheter having a six-dimensional location

18   capability in accordance with a preferred embodiment of the

19   present invention;

20   Fig. 3 is a more graphic illustration of a portion of

21   the probe showing a preferred embodiment of a sensor for

22   six-dimensional location;

23   Fig. 4 is a block diagram of circuitry used to

24   determine the six-dimensional coordinates of a catheter, in

25   accordance with a preferred embodiment of the invention;

26   Fig. 5 shows in expanded detail the basic flow chart

27   representing a control sequence and its application to the

28   block diagram of Fig. 4, in accordance with a preferred

29   embodiment of the invention;

30   Fig. 6 is a block diagram representing digital signal

31   processing in the signal processor in accordance with a

32   preferred embodiment of the invention;

33   Fig. 7 is a three-dimensional graphic representation of

34   the vectors forming the magnetic field at a point;

35   Fig. 8 is a block diagram representing analog signal

36   processing in the signal processor, in accordance with a

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1 preferred embodiment of the invention;

2   Fig. 9 is a simplified schematic of an analog filter

3 element shown in Fig. 8, in accordance with a preferred

4 embodiment of the invention;

5   Figs. 10A-10D illustrate a principle of orienting the

6 tip of a catheter in accordance with a first preferred

7 embodiment of the invention;

8   Fig. 11 illustrates a principle of orienting the tip of

9 a catheter in accordance with a second preferred embodiment

10 of the invention;

11   Fig. 12 is a block diagram of ultrasonic acquisition

12 and signal processing circuitry in accordance with a

13 preferred embodiment of the invention;

14   Fig. 13 is a block diagram of image reconstruction

15 circuitry in accordance with a preferred embodiment of the

16 invention;

17   Fig. 14 is a partially schematic, partially cut-away

18 illustration of a probe for electrical sensing, pacing and

19 ablation in accordance with a preferred embodiment of the

20 invention;

21   Fig. 15 is a schematic block diagram for acquiring a

22 basic electrogram map in accordance with a preferred

23 embodiment of the present invention;

24   Fig. 16 is a schematic block diagram representing a

25 computerized endocardial mapping algorithm, in accordance

26 with a preferred embodiment of the invention;

27   Fig. 17 is a schematic block diagram representing a

28 computerized pace mapping algorithm, in accordance with a

29 preferred embodiment of the invention;

30   Fig. 18 is a schematic block diagram of an algorithm

31 used to calculate the cross-correlation index while pace-

32 mapping, in accordance with a preferred embodiment of the

33 invention; and

34   Fig. 19 is a schematic block diagram representing an

35 output configuration of an imaging system in accordance with

36 a preferred embodiment of the invention.

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DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

1
2   Figure 1 shows a pictorial representation of a basic
3 preferred application of the invention to the human body. In
4 this application, a catheter 10 is inserted into an artery
5 11 of a patient using standard techniques. Catheter 10
6 comprises a body 12, a locating sensor 14 and an active
7 portion 16 at the distal end 15 of the catheter. The active
8 portion 16, in accordance with various preferred embodiments
9 of the invention, may include an electrical sensor, an
10 ultrasound head, a fiber optic viewing head, an electrical
11 stimulator, an electrical or laser ablator, an ionic sensor,
12 an oxygen or carbon dioxide sensor, an accelerometer, a
13 blood pressure or temperature sensor or a cryogenic probe.
14 In general the catheter will include leads, light guides,
15 wave guides, etc. for energizing the active portion in
16 response to commands of an operator.
17   The position and orientation of the distal end of the
18 catheter is ascertained by determining the position of the
19 locating sensor. In a preferred embodiment of the invention,
20 the locating sensor comprises two or three antennas, for
21 example coils which are irradiated by two or three radiators
22 18, 20 and 22, which are outside the body surface 23 of the
23 patient.
24   It should be understood that placement of the
25 radiators, as well as their size and shape, will vary
26 according to the application of the invention. Preferably
27 the radiators useful in a medical application comprise wound
28 annular coils from about 2 to 20 cm in diameter (O.D.) and
29 from about 0.5 to 2 cm thick, in a coplanar, triangular
30 arrangement where the centers of the coils are from about 2
31 to 30 cm apart. Bar-shaped radiators or even triangular or
32 square-shaped coils could also be useful for such medical
33 applications. Moreover, in instances where a prone patient
34 will be the subject of a procedure involving the instant
35 technology, the radiators are preferably positioned in or
36 below the surface upon which the patient is resting,

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1 substantially directly below the portion of the patient's
2 body where a procedure is being performed. In other
3 applications, the radiators may be fairly close to the skin
4 of the patient.

5   The three radiators are driven by a radiator driver
6 24, preferably in a manner described below, and the signals
7 received by the receiving antennas are amplified and
8 processed, together with a representation of the signals
9 used to drive radiators 18, 20 and 22, preferably in the
10 manner described below, in a signal processor 26 to provide
11 a display or other indication of the position and
12 orientation of the distal end 15 on a monitor 27.

13   Radiators 18, 20 and 22 may be arranged in any
14 convenient position and orientation, so long as they are
15 fixed in respect to some reference frame, and so long as the
16 radiators are non-overlapping, that is, there are no two
17 radiators with the exact, identical location and
18 orientation. When driven by radiator driver 24, the
19 radiators generate a multiplicity of distinguishable AC
20 magnetic fields that form the magnetic field sensed by
21 receiving antennas in the locating sensor.

22   The magnetic fields are distinguishable with regard to
23 the frequency, phase, or both frequency and phase of the
24 signals in the respective magnetic fields. Time multiplexing
25 is also possible.

26   In practice the active end of the catheter may be used
27 to gather information, such as ultrasound echo information,
28 electrical activity information etc., and optionally to
29 perform certain procedures on the arteries (or veins) or
30 within an organ chamber 28 to which the artery (or vein)
31 leads. Particular examples of organ chambers are the
32 chambers of the heart, brain or gastrointestinal tract. It
33 is a particular object of some aspects of the present
34 invention to more accurately map the electrical activity of
35 the heart and to more accurately image the walls of the
36 heart, as will be described in more detail below.

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1   Fig. 2 shows a schematic illustration of a preferred
2 embodiment of the distal end of catheter 10. A graphic
3 illustration of locating sensor 14 is shown in Fig. 3.
4 Sensor 14 preferably includes two or more and more
5 preferably three sensor coils 30, 32 and 34 wound on air
6 cores. In a preferred embodiment of the invention the coils
7 have mutually orthogonal axes, one of which is conveniently
8 aligned with the long axis of the catheter. Unlike prior art
9 location sensors (used for other applications) which contain
10 three coils that are concentrically located, or at least
11 whose axes intercept, the coils of the preferred embodiment
12 of the invention are closely spaced along the axis of the
13 catheter to reduce the diameter of the locating sensor and
14 thus make the sensor suitable for incorporation into a
15 catheter.
16   For most aspects of the present invention, quantitative
17 measurement of the position and orientation of the catheter
18 distal end relative to a reference frame is necessary. This
19 requires at least two non-overlapping radiators that
20 generate at least two distinguishable AC magnetic fields,
21 the radiators' respective positions and orientations
22 relative to the reference frame being known; a radiator
23 driver which preferably continuously supplies the radiators
24 with AC signals to generate the AC magnetic fields; and a
25 location sensor, consisting of at least two non-parallel
26 sensors to measure the magnetic field flux resulting from
27 the at least two distinguishable magnetic fields. The
28 number of radiators times the number of sensors is equal to
29 or greater than the number of degrees of freedom of the
30 desired quantitative measurement of the position and
31 orientation of the sensors relative to the reference frame.
32   Since, in a preferred embodiment of the invention it is
33 preferred to determine the six position and orientation
34 coordinates of the distal tip of the catheter, at least two
35 coils are required in location sensor 14. Preferably three
36 coils are used to improve the accuracy and reliability of

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1   the position measurement. In some applications where fewer

2   dimensions are required, only a single coil may be necessary

3   in locating sensor 14.

4   Leads 36 are used to carry signals detected by the

5   sensor coils to signal processor, via the proximal end of

6   the catheter, for processing to generate the required

7   position information. Preferably, leads 36 are twisted pairs

8   to reduce pick-up and may be further electrically shielded.

9   In a preferred embodiment of the invention, coils 30,

10   32 and 34 have an inner diameter of 0.5 mm and have 800

11   turns of 16 micrometer diameter to give an overall coil

12   diameter of 1-1.2 mm. The effective capture area of the coil

13   is preferably about 400 mm². It will be understood that

14   these dimensions may vary over a considerable range and are

15   only representative of a preferred range of dimensions. In

16   particular, the size of the coils could be as small as 0.3

17   mm (with some loss of sensitivity) and as large as 2   or

18   more mm. The wire size can range from 10-31 micrometers and

19   the number of turns between 300 and 2600, depending on the

20   maximum allowable size and the wire diameter. The effective

21   capture area should be made as large as feasible, consistent

22   with the overall size requirements. While the preferred

23   sensor coil shape is cylindrical, other shapes can also be

24   used. For example a barrel shaped coil can have more turns

25   than a cylindrical shaped coil for the same diameter of

26   catheter. Also, square or other shaped coils may be useful

27   depending on the geometry of the catheter.

28   Leads 38 are used to power active portion 16 and/or to

29   receive signals therefrom. The nature of leads 38, which may

30   vary and may, for example, include an optical waveguide or

31   other transmission media as appropriate to their task.

32   For example, an electrode located on the distal tip of

33   the catheter records local cardiac electrical activity, for

34   example, on the endocardium.   These local electrograms

35   (ECG's) are transferred via leads 38 to the proximal end of

36   the catheter and fed into an ECG amplifier.   The amplified

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1   ECG signals are transferred to the control system that
2   presents to the physician the local electrogram morphology
3   acquired from the site whose location was determined at the
4   same time.

5   Figure 4 is a block diagram of preferred circuitry used
6   in computing the position of locating sensor 14. In this
7   exemplary embodiment, three radiators 18, 20 and 22 and
8   three sensor coils 30, 32 and 34 are used. Radiator driver
9   24 provides distinguishable, simultaneous AC current signals
10   to each radiator. Control circuitry 40 utilizes D/A
11   convertors 42, 44 and 46 to generate three sine waves of
12   three different frequencies, f_1, f_2 and f_3, which are output
13   separately to signal amplifiers 48, 50 and 52.

14   In order to achieve a fast response locating system the
15   use of slow responding filters has been eliminated by using
16   cross-correlation of the radiated and the received signals.
17   This cross-correlation is performed over a window in time
18   which contains an integer number of the cycle lengths of the
19   three radiated signals. Use of an integer number of cycles
20   generally results in a decrease in processing errors and a
21   more accurate determination of the relative amplitude and
22   phase of the signals received by the sensor coils. If non-
23   integral cycle lengths are used an error in the cross-
24   correlation generally results, unless a very long
25   correlation window is used.

26   If a short correlation window is used, (the shortest is
27   the minimal common product of the cycle times), the ratio
28   between frequencies should be a rational number. The
29   frequency of a radiator c, f_c, where c = 1, 2 or 3 should
30   satisfy the equation:

31                    $$f_c = n_c \cdot f_b \qquad (1)$$

32   where n_c is any positive integer such that n1 ≠ n2, n2 ≠ n3,
33   and n3 ≠ n1, and f_b is an arbitrary base frequency to assure
34   that integral cycle lengths can be used for cross-
35   correlation.

36   The radiating driver amplifier output signals are

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1 delivered to the radiators through current sensitive
2 circuitry 54, 56 and 58, such as a resistor, loop or more
3 sophisticated circuitry as is known in the art. The current-
4 sensitive circuitry produces an output which represents the
5 amplitude and phase of the driving signal for the radiators
6 and which is passed to signal processor 26. With this
7 arrangement, the three radiators will generate a magnetic
8 field composed of three differently oriented field
9 components each having a different known frequency. Each of
10 these field components will be sensed by each of sensor
11 coils 30, 32 and 34 which will each produce a signal
12 composed of three frequency components having different
13 amplitudes and phases depending on the relative distance and
14 orientation of the particular sensor coil and particular
15 radiator which radiates a particular frequency.
16   The outputs signals of sensors 30, 32 and 34 are
17 amplified in amplifiers 60, 62 and 64 respectively and
18 passed on to signal processor 26.
19   Fig. 5 shows in expanded detail the basic flow chart
20 representing a control sequence and its application to the
21 circuitry of Fig. 4. During the initialization phase,
22 indicated by block 66, the frequencies of the three sine
23 waves, the physical position and orientation of radiators
24 18, 20 and 22 in respect to a reference frame, the
25 properties of the radiators and sensors and the coordinates
26 of a single point in the mapping field are defined. Sine
27 waves having respective frequencies f_1, f_2 and f_3 are
28 synthesized as indicated by block 68, for example in control
29 40. These generated frequencies are transmitted, preferably
30 continuously, by radiators 18, 20 and 22 as indicated by
31 block 70 and as described above with reference to Fig. 4.
32 The control sequence enters a timing loop 72 that
33 periodically sends signals to activate the signal processor
34 to cross-correlate the coil sensor signals with the radiated
35 signals and to calculate the orientation and position of
36 locating sensor 14 relative to the reference frame.

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1   Both analog and digital embodiments of signal
2   processing are possible in accordance with preferred
3   embodiments of the invention. These different approaches can
4   be modified in a variety of ways by those skilled in the
5   art, and can be combined in different modes in order to
6   practice them simultaneously. Some applications of the
7   present invention would benefit from the digital approach,
8   while the analog approach may be the preferable solution in
9   other cases.
10   The digital embodiment is described in conjunction with
11   Fig. 6, which is a functional block diagram of signal
12   processor 26. The inputs to the processing block are the
13   signals from amplifiers 60, 62 and 64 (the sensor coil
14   signals) denoted by SIG and inputs from current sensing
15   circuits 52, 56 and 58 denoted as CUR. In this embodiment
16   the six input signals are converted from analog to digital
17   signals by an array of A/D converters 74. The sampled
18   digital signals are passed to the "calculate cross
19   correlation" block 76, which may consist of dedicated
20   circuitry or which may be performed by a dedicated or shared
21   microprocessor. Using the six data streams (three AC
22   currents flowing through the radiators and three sensor
23   readings) the cross correlation elements can be calculated
24   using the following method:
25
26   Given that
27   SIG_s is the amplified output of sensor s, where s = 1,
28   2 or 3;
29   CUR_c is the current flowing through radiator c, where
30   c= 1, 2 or 3;
31   f_b is an arbitrary base frequency;
32   f_0 is the sampling frequency which is an integral
33   multiple of f_b; and
34   and N is the correlation length in number of samples,
35        $N=K(f_0/f_b)$, where K is any positive integer,
36   the correlation between CUR_c and the sine wave of frequency

- 21 -

1   f_c is:

2

3       $A_c^I = (2/N) \cdot \sum CUR_c[i] \cdot \sin(2\pi f_c(i/f_0))$;   (3)

4

5   and the correlation between CUR_c and the cosine wave of

6   frequency f_c is:

7

8

9

10      $A_c^Q = (2/N) \cdot \sum CUR_c[i] \cdot \cos(2\pi f_c(i/f_0))$;   (2)

11

12 where both summations are taken over i from 1 to N.

13 The correlation between SIG_s and the sine wave of frequency

14 f_c is

15

16      $B_{s,c}^I = (2/N) \cdot \sum SIG_s[i] \cdot \sin(2\pi f_c(i/f_0))$;   (4)

17

18 and the   correlation between SIG_s and the cosine wave of

19 frequency f_c is

20

21      $B_{s,c}^Q = (2/N) \cdot \sum SIG_s[i] \cdot \cos(2\pi f_c(i/f_0))$;   (5)

22

23 where both summations are taken over 1 from 1 to N.

24   A preferred ratio of f_1, f_2 and F_3 is 1, 2, 3 and

25 preferred frequencies are 1, 2 and 3 kHz. The useful

26 frequency range is believed to lie between 50 Hz and 50 kHz.

27   The calculation of the fields and currents, designated

28 by block 78, can also be performed using either dedicated

29 circuitry or a dedicated or shared microprocessor. The

30 amplitude of the current through each radiator A_c can be

31 calculated using:

32

33          $A_c = |A_c^I + jA_c^Q|$ (6)

34

35 and the magnitude of the field generated by each radiator,

36 $|B_{s,c}|$, can be calculated using:

- 22 -

1           $|B_{s,c}| = |B_{s,c}^I + jB_{s,c}^Q|$ (7)

2

3   The phase between the current in radiator c and the

4   field sensed by sensor s, $\Psi_{s,c}$, is

5

6   $\phi_{s,c} = arg(B_{s,c}^I + jB_{s,c}^Q) - arg(A_c^I + jA_c^Q) - \Psi_s^0$ (8)

7.

8   where Ψ_s^0 is the phase delay between the radiated field and

9   the field as read by sensors s. The amplitude of the field

10 generated by radiator c as sensed by sensor s is:

11

12      $B_{s,c} = |B_{s,c}|$,   if $|\phi_{s,c}| < 90°$ (9A)

13      $B_{s,c} = - |B_{s,c}|$, if $|\phi_{s,c}| \geq 90°$ (9b)

14

15   The magnetic field for every possible location and

16 orientation of the sensor in the mappable space can be

17 obtained by using:

18   1) The field equations of the radiators used in a

19 specific embodiment,

20   2) The exact position and orientation of the radiators,

21 and

22   3) The current flowing through the radiators A_c.

23   Preferably the contributions of each field generator

24 are used to solve a set of field equations, which are

25 dependent upon the field form. Solving these equation sets

26 produces the location and orientation of the remote sensors,

27 most preferably simultaneously.

28   More particularly, the field equations are derived

29 specifically for each embodiment and are dependent on the

30 geometry and characteristics of the radiators.   In the

31 preferred embodiment of the invention where the radiators

32 are coils, the field equations can be described as follows:

33   For a coil with N turns a radius R and a current I, the

34 radial field component at a distance r is

35

36 $B_r(I, \vec{r}, cos\theta) = (2\pi R^2 10^{-7} \cdot NI/r^3) \cdot$

- 23 -

$$\sum (2i+1) P_{2i}(0) \cdot (R/r)^{2i} \cdot P_{2i+1}(\cos\theta) \quad (10)$$

and the tangential field component is:

$$B_\theta(I, \vec{r}, \cos\theta) = (2\pi R^2 10^{-7} \cdot NI/r^3) \sum P_{2i+2}(0)(R/r)^{2i} P_{2i+1}^1 \cos\theta$$

where the sums are from $l=0$ to $i=\infty$ and where $P_n(x)$ is a Legendre Polynomial of degree n, and calculated recursively by:

$$P_0(x) = 1$$
$$P_1(x) = x \qquad\qquad\qquad\qquad\qquad (12)$$
$$P_n(x) = 1/n \ [(2n-1) \ x \ P_{n-1}(x) - (n-1) \ P_{n-2}(x)]$$

$P_n^1(x)$ is a generalized Legendre Polynomial of degree n, and calculated by:

$$P_n^1(x) = -(n+1) \cdot x \cdot (P_n(x) - P_{n-1}(x))/(1-x^2)^{\frac{1}{2}} \text{ for } |X| < 1$$
$$= 0 \qquad\qquad \text{ for } |X| = 1 \qquad (13)$$

These field equations are correct for $r>R$ for a radiator located in location $\vec{P}$. The field induced at location $\vec{K}$ is, as shown in Fig. 7, given by:

$$B = B_u \hat{O} + B_w \hat{W}$$
$$B_w = B_r \sin\theta + B_\theta \cos\theta \qquad\qquad (14)$$
$$B_u = B_r \cos\theta - B_\theta \sin\theta$$

where $\hat{O}$ is a unit vector in the radial direction of the radiator located at $\vec{P}$ and $\hat{W}$ is a unit vector in the tangential direction of the radiator located at $\vec{P}$. Using this general field equation one can calculate the field at point $\vec{K}$ generated by each of the radiators.

The remote sensor orientation, denoted by $\hat{V}$ determines the field sensed by this sensor at this location ($\vec{K}$).

$$B \cdot \hat{V} = B_{\hat{V}} \qquad\qquad (15)$$

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1   Therefore the field sensed by a remote sensor is

2

3       $B_{\hat{V}} = B(\hat{P}, \hat{O}, I, \hat{K}, \hat{V})$ (16)

4   where $\hat{K}$ and $\hat{V}$ are the unknown variables, and $\hat{O}$, $\hat{P}$ and I are

5   the known variables for any given coil.

6   In the example embodiment there are three radiators;

7   therefore there will be three known values of $\hat{P}$ and three

8   known values of $\hat{O}$. The three sensors have a fixed and known

9   location and orientation in the remote object reference

10   frame. For each position and orientation of the remote

11   object, one can compute the location and orientation of each

12   sensor in the radiator reference frame and therefore compute

13   the field sensed, B_V, for each radiator and each sensor. In

14   the case of the present location system, each field sensed

15   by each sensor from every radiator is measured and the field

16   equations are solved to obtain the location and orientation

17   of the remote object (x, y, z, ε, ξ, and ζ).

18   The results of this approach for the three radiator,

19   three sensor system used here as an example, are nine non-

20   linear algebraic equations with six variables (namely, x, y,

21   z of the sensing means position and ε, ξ, and ζ for the

22   location sensor orientation) in the form of:

23

24       $([F_{s,c} (x,y,z,\varepsilon,\xi,\zeta) = B_{sc}]_{s=1,2,3})_{c=1,2,3}$ (17)

25

26   In this embodiment of the invention, the nine sensor

27   readings ($B_{s,c}$) are the measured quantity, and by solving

28   this overdetermined system of equations (using a variety of

29   known numerical methods such as the Newton-Raphson method

30   for non-linear systems of equations or Multidimensional

31   Secant Methods, specifically Broyden's method), the location

32   and orientation of location sensor 14 is determined. A

33   description of several possible numerical methods for

34   solving such a set of equations is found in William H. Press

35   et al, "Numerical Recipes in C. The Art of Scientific

36   Computing", second edition, Cambridge University Press,

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1 1992.   The location sensor position and orientation are

2 displayed on monitor 27.

3   An ECG monitor may be used to synchronize the

4 acquisition of the signals from the sensor coils so as to

5 remove cardiac motion artifacts from the position

6 information. Furthermore, a reference sensor may be attached

7 to a portion of an organ being tested or treated, such as

8 the heart, which will be used to correct for breathing

9 motion or patient movement. In this way, the acquired sensor

10 positions may be referenced to the organ structure and not

11 to an absolute outside reference frame, which is less

12 significant.

13   In an analog based embodiment of signal processor 26,

14 some of the parameters are calculated using analog

15 circuitry. Fig. 8 is a schematic of one analog based

16 embodiment of signal processor 26. In this embodiment,

17 three sine and three cosine wave signals of frequency f_1,

18 f_2, and f_3, are used in addition to the SIG and CUR signals

19 used in the embodiment of Fig. 6. The SIG and CUR signals

20 are filtered by 12 phase sensitive filters (correlators) 80,

21 such as are shown in Fig. 9 to produce signals indicative of

22 the sine and cosine components of the SIG and CUR signals.

23   These analog signals are then passed to a set of A/D

24 converters 82. The fields and currents and positions are

25 calculated in the same manner as described above with

26 respect to Fig. 6.

27   Fig. 9 shows the expanded view of one possible

28 embodiment of one of the analog filter elements of Fig. 8.

29 Each analog filter unit has three inputs; a cosine wave

30 $\cos(2\pi f_c)$, a sine wave $\sin(2\pi f_c)$, and the signal, either one

31 of SIG_s or CUR_s from which the frequency component f_c is to

32 be extracted. Within the analog filter unit the signal is

33 multiplied by $\sin(2\pi f_c)$ and $\cos(2\pi f_c)$ in multipliers 84 and

34 86. The results are passed through low pass filters 88 and

35 90 to obtain the desired components of the signal.

36   The description above primarily concerns acquiring

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1 information by a set of two or more sensors that is used to
2 determine the position and orientation of a remote object or
3 a point on a remote object such as a medical device or
4 instrument. It is also within the scope of the invention
5 that a remote object will have more than one set of sensors,
6 preferably from 2 to 6 sets of sensors, that will provide
7 sufficient parameters to determine the shape and/or
8 configuration of a remote object, preferably relative to a
9 reference frame. For example, if the catheter has
10 additional sets of sensors located proximal to its distal
11 tip, it would be possible to determine the shape and/or
12 configuration of portions of the catheter. Similarly, for
13 another invasive procedure such as a sigmoidoscopy or
14 colonoscopy, it may be possible to determine the shape
15 and/or configuration of some or all of the scope used.

16   The equipment necessary to practice the invention is
17 mostly conventional. In one embodiment of the invention,
18 the controller is a simple off-the-shelf 486 IBM compatible
19 computer. The A/D boards are commercially available and
20 have the characteristic of being able to sample at least 8
21 channels with a sampling frequency of between 500 - 40,000
22 samples per second on each channel. An example of such an
23 A/D Board is the National Instruments AT-MIO-16X that is
24 available from National Instruments, Texas, USA. The D/A
25 function is achieved using commercially available 8-21 bit
26 resolution D/A boards. Examples of such a D/A are the
27 National Instruments A/D,D/A Board AT-MIO-16X or National
28 Instruments DSP model AT-DS2200. The radiation driver
29 amplifiers are commercially available, with 2-16 ohms
30 output impedance and an output power of 60-500 watts. An
31 example of such amplifiers is the Inkel amplifier type NA-
32 420, from Inkel of Seoul, Korea. The radiators are also
33 commercially   available and have the following
34 characteristics: 1-6 cm radius, 0.5-3 cm thickness, and
35 100-500 turns made of copper wire of diameter 0.1 -0.95 mm.
36 A specific example of such a coil could be coils having a 4

- 27 -

1　cm radius, 1 cm thickness with 151 turns of copper wire of

2　0.41 mm diameter.

3　　　While the sensor described above is preferred, other

4　sensors may be suitable for some applications, such as Hall

5　effect sensors, for example those available from Allegro

6　Micro Systems, Inc., USA or magneto-resistor sensors,

7　sensors, flux gate magnetic sensors, and/or other magnetic

8　flux sensors.

9　　　Controller 40 represents an assemblage of units to

10　perform intended functions. For example, such units may

11　receive information or signals, process information,

12　function as a controller, display information, and/or

13　generate information or signals. Typically controller 40

14　may comprise one or more microprocessors.

15　　　In accordance with a preferred embodiment of the

16　invention, active portion 16 of catheter 10 is a forward

17　looking ultrasound send/receive transducer. Such a

18　transducer can give a one-dimensional map of the acoustic

19　properties of the material lying in front of it by radiating

20　a focused beam of pulsed acoustic energy and then measuring

21　the echoes of the beam reflected by changes in acoustic

22　properties along the path of the beam. In order to provide a

23　three dimensional image it is necessary to change the

24　direction of the beam, preferably without changing its

25　position by a great amount.

26　　　In particular, such a steerable, one dimensional

27　acoustic transducer can be used to map the heart walls or

28　blood vessels, ultrasonically, from inside the heart. When

29　coupled with a reference location sensor at a reference

30　point on the heart and ECG gating of the acoustic pulses,

31　such a transducer can generate the information required to

32　form a three dimensional image of the heart or blood vessels

33　or any other organ, at one or several different phases of

34　the heart cycle.

35　　　The principle of two preferred embodiments of a

36　steering mechanism are shown in Figs. 10A-10D and 11

- 28 -

1 respectively. Fig. 10A shows a steering mechanism 92 that
2 fits into the distal end of a catheter and comprises two
3 steering wires 94 attached to a steering head 96. Head 96 is
4 formed of a relatively flexible material such as stainless
5 steel and is slit along its axis, each side of the split
6 being attached to one of wires 94. Such a head may be
7 manufactured by attaching two wires (94) at their end and
8 then flattening the wires to form a more easily bent
9 structure.
10   Attached to the distal end of the steering head is a
11 relatively rigid housing containing locating sensor 14 and
12 active portion 16 which, in the present preferred
13 embodiment, is an ultrasonic send/receive transducer. At
14 least head 96 and wires 94 are encased in a catheter sheath
15 104 which is not shown in Figs. 10A-10C for clarity of
16 presentation. This steering mechanism can also be used for
17 other active portion types such as for electropysiologic
18 mapping procedures and for improved steering of catheters or
19 many types, with or without location sensing.
20   In Fig. 10B one of wires 94 has been shortened as
21 compared with the other wire. Since the catheter sheath
22 holds the wires together, the result of such shortening of
23 one wire is bending of the head, which is facilitated by the
24 axial slit. Locating sensor 14 and active portion 16 are
25 rigidly attached so that measurement of position and
26 orientation of the locating sensor will give the position
27 and orientation of the active portion (ultrasound
28 transducer). By varying the angle of bending and rotating
29 the catheter, imaging over nearly 360° image can be
30 achieved. Additionally or alternatively, as shown in Fig.
31 10C, the amount of rotation can be reduced by shortening the
32 other wire and which causes bending in the other direction.
33 Slight motion of the transducer can be corrected by a simple
34 translation of the acquired one dimensional image associated
35 with the particular position.
36   Fig. 10D shows a mechanism 98 placed at the proximal

- 29 -

1 end of the catheter for changing the relative lengths of
2 wires 94. A handle 100 comprises a housing 102 to which
3 catheter sheath 104 is attached. The proximal end of wires
4 94 are formed in a loop (for example by welding the ends of
5 the wire) and wrapped around a spindle 106 which is
6 preferably fixed and which forms a frictional contact with
7 the wires.

8   A lever 108 is rotatably attached near its center at a
9 pin 110 to the housing and is attached at one end to wire 94
10 and at the other end to a slider 112 which is slidable
11 parallel to the housing. When the slider is moved, one of
12 the wires 94 at the distal end is lengthened with respect to
13 the other.

14   Fig. 11 shows the distal end of a catheter having an
15 alternative steering mechanism. A relative rigid sleeve 114
16 is placed within cathode sheath 104. Sleeve 114 can be
17 axially displaced relative to the sheath from the proximal
18 end of the catheter.

19   The distal end of sleeve 104 is formed with a disk 116
20 through which a relatively less rigid wire 118 passes. Wire
21 118 is formed with a permanent bend near its distal end at
22 which end, position sensor 14 and active portion 16 are
23 attached. Axial movement of sleeve 104 straightens wire 118
24 resulting in a change in orientation of both the position
25 sensor and the active portion. If wire 118 is sited off
26 axis, then rotating the wire will rotate the catheter.

27   It should be understood that steering of acoustic beams
28 may also be achieved by a moving mirror or by a phased array
29 ultrasonic transducer, and that such a mirror or other
30 arrangement may be present in the active portion. Such
31 active scanning may supplement or replace the passive
32 steering provided by the mechanisms of Figs. 10 and 11.

33   Fig. 12 shows a simplified system block diagram of
34 ultrasonic acquisition and image formation in accordance
35 with a preferred embodiment of the invention. An image
36 sensor 120, such as the ultrasound sensor described above,

- 30 -

1   transmits an acoustic pulse 122 in response to a signal

2   received from a transmitter driver circuit 124. An acoustic

3   echo 126 (generally comprising several echoes) is received

4   by the image sensor which produces an echo signal, which

5   when amplified, is sent to a receiver processing circuit 128

6   which generates a one dimensional "image" at its output 130.

7   Information identifying the heart phase of the image may

8   also be present at output 130 which may comprise a plurality

9   of output ports. In one embodiment of the invention,

10   especially useful for heart imaging, the acquisition of the

11   image is made in response to signals received from an ECG

12   monitor 132. This allows for acquisition of images at a

13   particular portion of the heart cycle so that the various

14   one-dimensional images can be easily reconstructed into a

15   three dimensional image.

16   In particular, if the most significant echo is used as

17   the measure of the distance from the ultrasonic sensor to

18   the chamber along the measurement direction of the sensor,

19   then the collection of such distances (referenced to a

20   reference point in the chamber) will allow the

21   reconstruction of the surface morphology.

22   Fig. 13 shows a simplified block diagram of a three

23   dimensional image reconstruction system which utilizes a

24   series of one dimensional images generated by the circuitry

25   of Fig. 12 and continuous sensed location and orientation

26   information generated by the position locator and its

27   associated circuitry as described above. In general it is

28   useful to acquire the sensed location and orientation to

29   coincide with the acquisition of each one-dimensional image.

30   One of the various methods described above for steering the

31   distal tip of the catheter is used to acquire a plurality of

32   one dimensional images with a plurality of orientations. An

33   automatic mechanism may be used to continuously change the

34   orientation of the imaging head in accordance with the

35   principles of Figs. 10 and 11 and to rotate the catheter so

36   that operator intervention is not required.

- 31 -

1   An image reconstruction processor 132 orients and
2 references the individual one dimensional images in
3 accordance with the sensed location and orientation
4 information and forms a 3-D image which can be presented on
5 an image display 13 either in the form of a series of two
6 dimensional slices or a full three dimensional
7 reconstruction. When images at different points in the heart
8 cycle are acquired, the image displayed may be a cine image
9 of the reconstruction.

10   In a preferred embodiment of the invention a two
11 dimensional image is acquired by the ultrasound sensor which
12 can be a phased array of acoustic crystals of a single
13 crystal in conjunction with a mirror rotating about an axis
14 that deflects the ultrasonic beam in a predetermined path.

15   In a preferred embodiment of the invention active
16 portion 16 comprises a sensor for sensing electrical signals
17 generated at selectable positions on the heart. As described
18 below, such sensings of electrical signals can be used to
19 map the electrical activity of the heart. The active portion
20 may also include an electrode useful for pacing the heart
21 and/or for ablating a portion of the heart. Such ablation is
22 especially useful in the treatment of the most common lethal
23 cardiac arrhythmia, ventricular tachycardia (VT), i.e., very
24 rapid and ineffectual contractions of the heart muscle. VT
25 is the cause of death of approximately 300,000 people
26 annually. It is also useful in the treatment of other
27 arrhythmias.

28   A catheter useful for electrical mapping of the
29 heart/ablation is shown schematically in Fig. 14.

30   Active portion 16 comprises a conducting tip,
31 preferably of platinum, having a length of between 1-12 mm,
32 preferably about 2 mm. The tip is connected via a tip
33 electrode lead-in wire 138 to a switch at the proximal end
34 of the cathode which switches the tip to a source of voltage
35 for pacing or/ablating or to a detector for detecting
36 electrical signals generated by the heart. A conducting ring

- 32 -

1 electrode 136 is placed, proximal to locating sensor 14, on

2 the outside of catheter sheath 104 and is connected to

3 ground or to a recorder via a return lead 140. When used for

4 pacing, as described below, a 1-10 ma pulse is applied

5 between tip 16 and ring electrode 136. When used for

6 ablation RF energy at about 0.5 MHz and 10-100 V is applied

7 for 10-200 sec.

8   Locating sensor 14 is rigidly attached to the tip and

9 the sensor and tip may be manipulated by an eccentric wire

10 142. The twisted wire leads are preferably shielded by a

11 shield 144 to reduce pickup from the relatively high

12 voltages carried by leads 138 and 140.

13   Preferably, an electrically insulating heat shield 146

14 is placed between the tip and the locating sensor.

15   Fig. 15 is a schematic block diagram for acquiring a

16 basic electrocardiogram map in accordance with a preferred

17 embodiment of the invention. Using a transesophageal

18 echocardiograph in the preferred embodiment, a multiplane

19 image of the heart chambers is acquired prior to the mapping

20 study. The image is acquired only during a fiducial point

21 in time during the cardiac cycle. In the preferred

22 embodiment, the image is acquired at end-diastole in

23 response to an end diastole synch-signal. A three-

24 dimensional image of the heart chambers is reconstructed

25 indicating the endocardial morphology and the location of

26 one or more reference catheters within the heart chamber.

27 This image can be acquired by a 3-D transesophogal

28 ultrasound image, by a CT scanner, by an MRI scanner or by

29 other imaging techniques. The image can also be constructed

30 by touching the catheter to the surface of the chamber

31 (endocardium) in a number of places and measuring the

32 positions. These points can then be used to describe a ~~thee~~ three

33 ~~dimensionsional~~ dimensional surface which represents the chamber

34 surface.

35   In the previous PCT and US applications (PCT/US94/08352

36 filed July 20, 1994 and 08/094,539 respectively), in which

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1 fewer than six location and orientation values were
2 determined, reference locatable catheters were place at
3 three positions in the heart to form a reference plane
4 against which the position of the active catheter was
5 referenced. Preferably, these reference locatable catheters
6 were placed, for example, in the right ventricular apex, the
7 right atrial appendage, and the pulmonary artery at the
8 level of the pulmonary valve, respectively. When a
9 reference catheter having a location sensor 14 as described
10 hereinabove is used for reference purposes, only a single
11 sensor is required to define the relative location and
12 orientation of the mapping catheter. While any of these
13 locations can be used, it is presently preferred to place
14 the reference sensor in the distal coronary sinus.

15   Fig. 16 is a schematic block diagram for illustrating
16 the computerized endocardial activation mapping algorithm
17 (used during sinus rhythm mapping and during ventricular
18 tachycardia mapping). A visible or audible indicator
19 preferably indicates the beginning of a data point
20 acquisition.   Both   electrical   activity   and
21 location/orientation data are acquired for each point in
22 the map.

23   The acquisition of catheter location information is
24 shown in left branch of the block diagram of Fig. 16. The
25 mapper electrode is in steady and stable contact with the
26 endocardium. Stable contact is determined by measuring the
27 stability of the location reading, the stability of the
28 sensed electrograms and the impedance of the contact.

29   The position and orientation of the locating sensor in
30 the mapping catheter are determined continuously in
31 accordance with the method described above and are saved in
32 response to an end diastole synch signal. The mapper
33 catheter tip is localized relative to the reference catheter
34 by finding the difference in each of the six dimensions of
35 the location and orientation. Generally speaking, for the
36 present application the orientation of the mapper cathode is

- 34 -

1   not required, however, it must be acquired to properly

2   transform its location and orientation to an internal heart

3   coordinate system.

4   Simultaneously, the activation time of the heart at the

5   mapper cathode tip is determined as shown on the right side

6   of Fig. 16. First the local electrocardiogram at the tip of

7   the mapper catheter is acquired and the activation time is

8   calculated based on comparing the amplitude and slope of the

9   local electrocardiogram to a template or manually by the

10 user. The local activation time is then defined with

11 reference to the activation time measured by an ECG terminal

12 on the skin of the patient.

13   The process of data acquisition can be terminated by

14 the user, or can be evaluated by an "evaluate activation

15 map" algorithm described below, that examines the already

16 acquired activation map for the density of information

17 relative to the spatial gradient of activation times. This

18 algorithm can indicate the next preferable site for

19 activation time detection. The catheter is moved by the

20 user to the new site, and the process of mapping continues.

21   During VT a data point is determined about every 4 to 6

22 heart beats. Thus, approximately 15 to 25, typically about

23 20, data points can be determined each minute.

24   Fig. 17 is a schematic block diagram for illustrating

25 the computerized pace mapping algorithm. A visible or

26 audible indicator indicates the beginning of a data point

27 acquisition. Acquisition of position information is similar

28 to that for Fig. 16 except that the average mapper location

29 in the previous n heartbeats (n is the moving average window

30 duration) is calculated.

31   The right side of Fig. 17 shows the determination of

32 the ACI (AutoCorelation Index) in a pace mapping mode.

33   In a "pace mapping mode" an ECG processor acquires ECG

34 data while the patient's heart is paced by an external

35 source at a rate similar to the patient's arrhythmia cycle

36 length. The ECG data is also acquired from the body surface

- 35 -

1 electrograms, and the signals are stored as a segment of ECG

2 with a length of several cycles. The signal acquired is

3 subjected to automatic comparison with the patient's own VT

4 signal (see Fig. 18). The comparison between arrhythmia

5 morphology and paced morphology is performed in two stages:

6 First, the phase shift between the template VT signal and

7 the paced ECG morphology is estimated using minimal error or

8 maximal cross-correlation for two signals. Then, using this

9 phase shift estimated from an index ECG channel, the

10 similarity of the VT and the paced ECG morphology is

11 measured as the average of the cross-correlation or the

12 square error of the two signals of all channels recorded.

13   This two-stage calculation is repeated each time using

14 a different ECG channel as the index channel for determining

15 the phase shift.

16   At the end of this procedure the minimal error or the

17 maximal cross-correlation found will be reported to the

18 operator as the ACI of this pacing site.

19   Fig. 18 is a schematic block diagram illustrating an

20 algorithm used to calculate the cross-correlation index

21 while pace-mapping in accordance with a preferred embodiment

22 of the invention. Body surface ECG data is acquired at two

23 stages. First, during spontaneous or pacing induced VT, and

24 second, during pacing the endocardium at different sites.

25 The ECG data acquired during VT are signal averaged, and a

26 template is constructed (T_{ch}, for each channel recorded).

27 During endocardial pacing the ECG data is acquired, and the

28 same number of beats (N) is acquired to calculate the signal

29 averaged QRS (P_{ch}, for each channel recorded). The

30 algorithm then calculates the phase shift between P_{ch} and

31 Tch, which yields for the first channel the maximal cross-

32 correlation. This time shift is used to shift the remaining

33 channels and calculate for them the cross-correlation. All

34 cross-correlations for all channels are summarized and

35 stored. The algorithm then uses the next channel recorded

36 to calculate the time shift that will cause maximal cross-

- 36 -

1   correlation in this channel. Now this time shift is applied
2   for all cross-correlations between P_{ch} and T_{ch}, and again
3   all cross-correlations are summarized. This procedure is
4   repeated for all channels, and the maximal cross-correlation
5   achieved is used as the value of the cross-correlation of
6   the T_{ch} and the P_{ch} at this site on the endocardium.

7   FIG. 19 is a schematic block diagram for illustrating
8   the output configuration of the present embodiment.   A
9   quasi-static picture of the heart chambers is presented as
10 3-D reconstruction of a basic image acquired prior to or
11 during the study as previously described. Superimposed on
12 the image is the location of the mapping/ablation catheter
13 (corrected for the movement of the reference catheter) and
14 the current and previous information acquired from the
15 mapping study.   This information may include, when
16 appropriate, the activation times (presented using a color
17 code at each acquisition site) or cross-correlation index
18 (ACI) for each point in the pace map. Furthermore, the map
19 can represent in the color coding the duration of the local
20 electrograms, the presence of fragmented activity as well as
21 various other variables calculated by the electrophysiologic
22 processor.

23   The above principles can be applied for mapping other
24 structures of the body, for example, of the urinary bladder,
25 brain, or gastrointestinal tract.   Dependent upon the
26 examination technique, the catheter may be replaced by a
27 needle whose tip is the locatable sensor port.

28   At each stage (sinus rhythm mapping, pace mapping and
29 VT mapping) after each data point is acquired, all available
30 information is reassessed for two purposes: first, to
31 suggest to the operator the next site for data acquisition,
32 and second, to test the available information to propose a
33 site for ablation.

34   Two algorithms are running simultaneously to perform
35 this procedure:

36   (1)   Mapping guidance algorithm. This algorithm uses as

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1 an input the available mapped information of a certain
2 variable (e.g., local activation time during sinus rhythm).
3 The algorithm calculates the spatial derivative of the
4 mapped variable (i.e., activation time in this example) and
5 calculates the next best location for adding another data
6 point when the objective function is regularizing the
7 spatial gradients of the mapped variable. For example, this
8 algorithm will suggest that more data points be acquired in
9 areas in which the mapped variable is changing significantly
10 over a short distance.
11   The location suggested by the algorithm is be presented
12 to the operator as a symbol on the display. The same
13 display already shows the basic image of the heart chamber
14 and the current location of the mapping/ablation catheter.
15 Therefore, the operator will move the mapping/ablation
16 catheter to reach the suggested location for further data
17 acquisition.
18   This algorithm is most beneficial during VT mapping,
19 where the available time for data acquisition is limited by
20 the adverse hemodynamic effects of the arrhythmia.
21 Therefore, such an algorithm which examines the available
22 data points of a map in real-time and immediately suggests
23 the next site for acquisition is very useful.
24   (2) Prognosing likelihood of successful ablation
25 algorithm. This algorithm is a user-defined set of
26 hierarchical rules for evaluating the acquired information
27 such as the rules given immediately below. The operator is
28 expected to grade the importance of the specific information
29 acquired in the mapping/ablation procedure, as to its
30 likelihood to identify the correct site for ablation.
31   Grading of mapping results suggesting the likelihood of
32 successful ablation at that site (A = highly likely
33 successful and D = least likely successful):
34   (a) The identification of a typical re-entrant pathway
35 on VT mapping with an identifiable common slow pathway -
36 Grade A;

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1   (b)The identification of a site with over 90%
2   correlation index in the pace map - Grade B;
3   (c)   The identification of a site where VT was terminated
4   with a non-capture premature stimulus - Grade C; and
5   (d) The identification of pre-potential maps recorded
6   during VT, which are similar to diastolic potential maps
7   recorded during sinus rhythm - Grade D.
8   Other types of electrographic maps of the heart are
9   also possible. By use of variables determined from paced or
10 non-paced acquisitions of electrographic data, the following
11 additional maps can be generated:
12 (1) Sinus rhythm activation map (isochronal map);
13 (2) Diastolic potential occurrence time map
14 (3) Local latency isochronal map during pace mapping;
15 (4) Activation time isochronal map during VT; and
16 (5) Pre-potential isochronal map during VT mapping.
17   Also, the sites where VT was terminated by a non-
18 captured premature stimulus can be presented.
19   The acquisition of these maps and of other factors
20 suitable for mapping and procedures for their determination
21 as well as additional details of the above mapping
22 procedures can be found in the above mentioned U.S. Patent
23 Application Number 08/094,539 and PCT Application
24 PCT/US94/08352.
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